UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

12/23/98

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

Subject: HED Response to Day 30 Comments (Errors) for Disulfoton (Phase 2).

DP Barcode: 251724

Chemical# 032501
Case# 0102

From: David G Anderson, PhD
RRB-2, HED (7509C)

To: Philip Poli, CRM
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Thru: Alan Nielsen, BSS
RRB-2, HED (7509C)

The initial 30-day comment (Phase 1, error correction only) on the Disulfoton RED has been submitted by the registrant. It is more appropriate that HED respond to item number 3 and 5 listed in the comments from Bayer to Philip Poli, dated 12/8/98, "Response to Draft EFED and HED Reregistration Eligibility Decision (RED) Science Chapter for Disulfoton, List A Case 0102" under "Errors to be Considered in the EFED Chapter." In addition HED will respond to the comments listed under "Errors to be Considered in the HED Chapter." None of these comments affect the current HED risk assessment of disulfoton, however, they may affect aggregate risk assessment during Phase 4. The registrant's comments on Phase 1 and HED's responses (Phase 2) to the registrant's comments are show below.

Registrant's Comment:

1. Under Errors to be Considered in the EFED Chapter, item number 5: The drinking water component of the aggregate risk was not brought into the FQPA risk assessment due to a full risk cup resulting from a Tier I dietary assessment. Appendix 6 of the HED RED describes a drinking water assessment based on Tier II PRZM/EXAMS modeling. The OPP stated previously that results of these models using a stagnant pond should not be used in the assessments:

> "OPP wishes to emphasize that the GENEEC and PRZM/EXAMS modeling of an edge of field farm pond is not appropriate for generating accurate estimates of pesticides or degradates in actual drinking water, and **should not be used directly in computing aggregate exposures for purposes of estimating human risks**." Reference: OPP's Interim Approach for Addressing Drinking Water Exposure. Memorandum from Stephen Johnson to OPP Division Directors, November 17, 1997.
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> Therefore, the Agency should not use the modeling results for FQPA exposure estimates, either in the form of estimating direct exposure or to suggest that concentrations predicted

in water exceed a level of concern.

Impact on the assessment: Exposure estimates using PRZM/EXAMS modeling with a farm pond scenario should not be used to assess risk associated with drinking water. No relationship can be made between the resulting predictions and actual drinking water consumed by the American population.

HED's Response: The registrant is correct that HED does not use PRZM/EXAMS modeling estimates directly in computing aggregate exposure for purposes of estimating human risk. However, in the absence of adequate monitoring data on drinking water concentrations and ground water concentrations, the data from the PRZM/EXAMS and SCI-GROW models may be used to estimate a theoretical upper limit of drinking water concentrations in light of total aggregate exposure to that chemical for food, water and non-occupational (residential) sources. HED calculates a DWLOC (Drinking Water Level of Comparison) which is compared to the DWEC (Drinking Water Estimated Concentration) from GENEEC and SCI-GROW models. This issue will be further addressed during Phase 4 (Finalized Risk Assessment).

2. Under Errors to be Considered in the HED Chapter: The only deficiency noted in this chapter is in the area of plant metabolism. The Agency asked for additional information to upgrade the existing studies on lettuce, potatoes, soybeans, and wheat. This request is based on an EPA memorandum dated March 18, 1997, entitled Disulfoton (032501), Reregistration case 102 (CBRS No. 13715, DP Barcode No. D203210, MRID # 43222401) from John Abbotts to Paula Deschamp.

Bayer has already responded to this request with the submission of Bayer Report No. 107834 (MRID # 44342101) dated 7/24/97. As this report is already in the Agency's files, failure to include it in this review constitutes an error of omission.

The document suggests several areas for exposure reduction and the need for additional data. BAYER will work with the Agency over the several months to define which uses will be supported, discuss the various mitigation measures proposed and further refine the risk assessment of disulfoton. Additionally, BAYER has already initiated studies in several areas to cover the need for additional information suggested by the Agency. These studies include:

a. An anaerobic aquatic or anaerobic soil metabolism study and an aerobic aquatic metabolism study on disulfoton. BAYER is also considering studies that will characterize the fate of the sulfoxide and sulfone metabolites in soil and water.
b. A repeat acute neurotoxicity study in hens will be submitted by December 1999.
c. A Monte Carlo analysis for dietary exposure has been initiated and will be submitted within the next several months.
d. An updated material accountability study and the manufacturing information will be provided for the technical. BAYER will also provide the validated analytical methods for the 68% and 2% formulations by June 1999.

This represents BAYER's initial response to the HED and EFED chapters. Additional information concerning the risk assessment and supported uses will be provided during the public

response period. As this information becomes available, BAYER will work with the Agency to refine the risk assessment for disulfoton and address issues and concerns raised by the Agency or FQPA. If you have any questions, please contact either me or Dr. Premjit Halarnkar at (816) 242-2331.

HED's Response: The referenced study Bayer Report N. 107834 (MRID# 44342101) dated 7/24/97 is in review. This report was submitted during the preparation of the Product Chemistry and the Residue Chemistry Chapters for the Disulfoton RED. Review of this report (a response rather than a study) will completed during Phase 4 of the Reregistration Process. The registrant is correct in reporting that this failure to include this report is an error of omission.

In addition, HED acknowledges that additional studies are being submitted on (a) anaerobic aquatic or anaerobic soil metabolism, (b) a repeat acute neurotoxicity study in hens, (c) a Monte Carlo analysis for dietary exposure, (d) an updated material accountability study and the registrant will provide manufacturing information on the technical grade and provide valid analytical methods for 68% and the 2% formulations.

However, there were other issues listed in the Product Chemistry and Residue Chemistry Chapters of the RED for Disulfoton that the registrant may need to address.